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PRESCRIPTION DRUGS AND DISCOUNTS: THE PHARMACIST'S VIEW

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OBJECTIVES: Pharmaceutical companies have designed prescription drug coupons and copay cards (CCCs) programs to maintain brand name medication loyalty, especially for medications that have just, or are about to lose their patent. The objective of this study is to evaluate perceptions of retail pharmacists about coupon and copay card (CCC) programs. **METHODS:** Pharmacists in the state of Arkansas, USA, were surveyed online. Questions on 5-point likert scale focused on pharmacist's perceptions towards CCC's regarding benefits to patients, public health, medication compliance, pharmacist workload, as well as barriers to pharmacy practice. Chi-square and multivariate logistic models were used to analyze the data. **RESULTS:** Of the approximately 1200 subjects 325 took the survey. Excluding missing values, 214 subjects were included in final analysis. Of these, 56% were male, 47% were less than 35 years of age, and 46% worked in a franchise or chain pharmacy, 40% were located in urban or suburban areas, 60% were in semi-urban or rural areas. Regression results indicated that full-time pharmacist practicing in larger pharmacies and processing higher numbers of CCCs had more favorable views towards patient satisfaction with CCCs (all p-values<0.05). Most pharmacists were reluctant to express that CCCs saved patients money, were good for public health, or improved medication compliance. Most pharmacists agreed that CCCs increased pharmacy workload, however highly satisfied pharmacist with proper staffing disagreed. Female pharmacists were more likely to explain CCC use to patients. Pharmacists working in high-volume chain and urban environments were least likely to state difficulties processing CCC transactions. All p-values in regression results reported above were <0.05 with odds ratios ranging from 1.05 to 2.5 (note: individual p-values and odds ratios are too many to report because of word limit). **CONCLUSIONS:** With increasing prevalence of CCCs, this study provides key insights into perceptions of pharmacists.

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THE ROLE OF HEALTH SHOCKS IN LATE PART D ENROLLMENT

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OBJECTIVES: Enrollment in Medicare Part D is voluntary; however, mechanisms exist to encourage early enrollment and improve risk pooling, including a permanent premium penalty associated with delayed enrollment and restricted enrollment periods. This study examined whether a health shock would create adequate incentives to overcome the penalties associated with late enrollment. **METHODS:** Using enrollment and claims from a random 5% sample of Medicare beneficiaries from 2006 to 2008, we observed Part D enrollment decisions among beneficiaries who had failed to enroll in Part D at first eligibility (N=207,674). A health shock was defined as a hospital admission due to a drug-intensive chronic condition. Multivariable logistic regression examined the impact of a health shock on the probability of late Part D enrollment, controlling for beneficiary demographics, pre-existing chronic conditions, preventive service use, and admission to a facility. We also examined whether timing of the hospitalization relative to the next available enrollment period influenced the likelihood of Part D enrollment. **RESULTS:** Eighteen percent of beneficiaries in the cohort enrolled late into Part D. Initial and subsequent hospitalizations for drug-intensive conditions were associated with 5 and 7 percentage point increases in the probability of Part D enrollment, respectively (p<0.01). A gap from the time of hospitalization to the next coverage period was associated with a lower likelihood of enrollment among non-Low Income Subsidy (LIS) recipients, but had no relationship for LIS enrollment, which is not restricted to enrollment periods. **CONCLUSIONS:** Health shocks were associated with an increased likelihood of late Part D enrollment, but many beneficiaries remained without Part D coverage despite deterioration in their health status and expected increased need for drugs. Non-enrollees were forced to either absorb the full cost of medications or forgo them, which can have negative effects on health and, the potential to increase Parts A and B spending.

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EFFECT OF PLACEMENT OF WARNING INFORMATION ON OTC DRUG FACTS PANEL: IMPROVING EASE OF USE AND PURCHASE INTENTION

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OBJECTIVES: Order in which warning information is presented on the over-the-counter medication Drug Facts panel could enhance patient safety. This study assessed the effect of placement of warning information on OTC Drug Facts panel to provide guidance to the FDA in enhancing appropriate product use. **METHODS:** Two experimental labels (current and new) were developed from an existing marketed drug product by varying the sequence of information to- uses, directions, other information and warnings (new) vs uses, warnings, directions and other information (current). In this repeated measure experimental study, each participant evaluated labels on ease of use and purchase intention using an eleven point scale with appropriate scale anchors. The order in which participants viewed the label was randomized. Mean score for ease of use and purchase intention was contrasted between labels using match paired t-test. **RESULTS:** Of the 297 study participants (71% response rate), majority were males (60.4%) with a mean (±SD) age of 21.3 (±1.8) years. More than half (55%) indicating they often read labels, while 70% were currently not on any medications. The mean (±SD) scores were significantly (p<0.0001) higher for ease of use for the new (8.0±1.2) as compared to the current label design (6.8±1.2). Similarly the mean purchase intention were also significantly (p<0.0003) higher for the new label design (7.8±1.4) compared to current label (7.4±1.2). **CONCLUSIONS:** The prototype new label developed with congruent information where uses and directions were clustered and were followed by warnings was perceived better. This information can help guide the FDA to conduct more studies and develop policy changes as necessary to improve information comprehension from OTC Drug Facts panel.

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PERCEPTIONS AND BARRIERS TO PARTICIPATION IN CLINICAL RESEARCH OF PRIMARY CARE PHYSICIANS

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BACKGROUND: The number of physicians willing to participate in clinical research has been on the decline in the US and Europe for the last decade. This trend is contrary to projected research needs as a result of expanded regulatory requirements for post-marketing studies of new drugs and devices and the need for more comparative effectiveness data. The problem is further magnified when considering the need for research data from the front lines of primary medical care, where the majority of patients receive their initial and ongoing care. **OBJECTIVES:** The primary objective of this study is to assess primary care physician (PCP) perceptions toward practice-based clinical research and identify barriers they face when deciding to participate in projects. **METHODS:** A web-based survey was distributed to over 4000 PCPs over a 30-day period. Respondents were asked about demographics, practice type, practice size, and prior clinical research experience. Respondents were divided into two cohorts based on prior research experience. Respondents were asked to evaluate the value of clinical research and barriers to participation. **RESULTS:** Survey responses were received from 109 PCPs, who were divided into two cohorts based on overall research experience. The cohorts were well matched for age, gender, specialty, practice size, and patient volume. Approximately 40% of sites with minimal research experience responded negatively to the value of clinical research, its impact on patient care or benefit to patients. Over 50% reported that and that their patients would not be interested in participation in research, regardless of study design, nor would they be willing to refer patients to physicians conducting research in which they patient could benefit. **CONCLUSIONS:** Sponsors must work more diligently to demonstrate the value of practice-based research and create incentives in order to recruit community-based physicians for clinical research studies.

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OPIOID ABSTINENCE IN OPIOID DEPENDENT PATIENTS INFECTED WITH HCV IN TREATMENT WITH BUPRENORPHINE

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OBJECTIVES: HCV infection rates have been gradually increasing for the past 10 years in the US with drug injection being reported as a primary cause. Buprenorphine, with its unique pharmacological profile is a common form of treatment for opioid dependence. The aim of this analysis was to determine whether opioid-dependent patients infected with HCV and being treated with buprenorphine are less likely to achieve the same levels of opioid abstinence as those who are not infected. **METHODS:** The data for this investigation came from the National Drug Abuse Treatment Clinical Trial Network study 0003, where, after buprenorphine stabilization, the effects of a 7 versus a 28 day tapering schedule was compared . Missed urinalyses were coded as positive for opioids. Binary logistic regression models were used to test the likelihood of providing an opioid-positive urine at baseline (immediately following stabilization), and at the end of the treatment period. An ordered logistic regression model tested the presence of HCV on the total number of positive urine tests submitted during the treatment period. **RESULTS:** A total of 35.73%of the participants in the overall sample tested positive for the HCV antibody. At baseline, there was a 60% increase in the odds of HCV patients testing positive/missing for opioid use, relative to non-HCV participants. there was a significant effect of HCV status on the total number of opioid positive urines submitted during the treatment period. However, HCV status was not significantly associated with the likelihood of a positive/missing urinalysis at the end of the treatment period. **CONCLUSIONS:** Individuals infected with HCV are less likely to provide opioid-free urine samples while being treated for opioid dependence with buprenorphine. This is an important, albeit exploratory finding that could significantly aid in developing future treatment strategies in managing HCV-infected opioid-dependent patients.

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WHY DRUGS FAIL? WHAT COULD HAVE BEEN DONE?

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OBJECTIVES: Most accounts put the research and development cost of bringing a new drug to market close to $1B USD (Adams and Brantner, 2010; Dimasi, et al., 2003). At this price, manufacturers cannot afford to launch a product that fails to meet market expectations, yet often products do not perform as anticipated. This effort looks at high-profile FDA approvals and evaluates the market performance with particular emphasis on exploring the reasons drugs do not meet the predicted revenue targets in the first year of sales. **METHODS:** We examined the 2010 and 2011 drug approvals to select the most appropriate NME to examine. Using data from EvaluatePharma®, we compared the forecasted annual sales estimate just prior to launch with the actual annual sales in the first year on the market. For the products that failed to meet expectations we